K030527 1/2

MAY 2 0 2003

VIII. Appendix 2

A. 510(k) Summary

Table 1 - Administrative Information

Category:	Comments
Sponsor:	Lumenis, Inc. 2400 Condensa Street Santa Clara, CA 95051
Correspondent:	Andrea L. Ruth, RAC Senior Associate II, Regulatory Affairs
Contact Numbers:	408.764.3235
Device Common Name	Laser Powered Surgical Instrument (and Accessories)
Device Proprietary Name	Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems
Device Classification Name	Laser Surgical Instrument for Use in General and planstic Surgery and in Dermatology
Device Classification	21 CFR § 878.4810
Predicate Devices	IPL Quantum Family; VascuLight Family
Predicate Device Manufacturer(s)	Lumenis
Predicate Device Reference(s)	K020839
Predicate Device Classification Name(s)	Laser Surgical Instrument for Use in General and planstic Surgery and in Dermatology
Predicate Device Classification(s)	21 CFR §878.4810

Date Summary Was Prepared: February 15, 2003.

Description of the Device: Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems are comprised of the following main components:

* A light/laser system console (including software and control electronics);
* A control and display panel; and
* One or more attached hand-piece(s), which may have integrated skin cooling components.

Intended Use: The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems (and the delivery accessories that are used with them to deliver light and/or laser energy) are intended for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology.

Safety and Effectiveness Information: Clinical data was provided to demonstrate that the Lumenis Family of IPL and IPL/Nd:YAG laser (1064 nm) systems are safe and effective for their intended and indicated uses in the medical specialties of general and plastic surgery, and dermatology.

Conclusion: The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems were shown to be substantially equivalent to the predicate devices cleared in K020839. The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems has identical intended use, as well as functional and design features as the currently marketed predicate devices. The only change is expansion of labeled indications for use, which fall within the scope of the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2003

Ms. Andrea L. Ruth, RAC
Senior Associate II, Regulatory Affairs
Lumenis, Inc.
2400 Condensa Street
Santa Clara, California 95051

Re: K030527
Trade/Device Name: Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 14, 2003
Received: February 19, 2003

Dear Ms. Ruth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known): K030527

Device Name: Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems

Indications For Use:

The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems (and the delivery accessories that are used with them to deliver light and/or laser energy) are indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology as follows:

Intense Pulsed Light Energy/Wavelengths (515 - 1200 nm) are indicated for:

* The treatment of tattoos;
* The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides(freckles);
* The treatment of cutaneous lesions including warts, scars and striae;
* The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
* The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent[1], hair reduction in skin types I-V.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030527

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

[1] Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.

510(k) Number (if Known): K030527

Device Name: Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems

Continued from Previous Page

Nd:YAG Laser Wavelength (1064 nm) is indicated for the coagulation and hemostasis of vascular lesions and soft tissue, including:

* Treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1 – 4.0 mm diameter) of the leg.
* The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent[1], hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

The Real Time Chiller is indicated for use in cooling the epidermis at the treatment site prior to, during and after light or laser treatment in general surgery, plastic surgery and dermatology to:

* Reduce pain during and/or associated with light or laser treatment (via partial anesthesia from cooling);
* Reduce discomfort during and/or associated with light or laser treatment;
* Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light or laser treatment, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation;
* Allow the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions); and
* Reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)